Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

#### ANNEX II

## **Component Material Categories (CMCs)**

#### PART II

### REQUIREMENTS RELATED TO CMCS

This Part defines the component materials of which EU fertilising products shall solely consist. CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

- 1. An EU fertilising product may contain substances and mixtures, except<sup>(1)</sup>:
- (a) waste within the meaning of Directive 2008/98/EC,
- (b) substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
- substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,
- (d) by-products within the meaning of Directive 2008/98/EC,
- (e) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,
- (f) polymers,
- (g) compost, or
- (h) digestate.
- 2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006<sup>(2)</sup>, with a dossier containing:
- (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
- (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, or 9 of Annex V to that Regulation.

- 3. Where the substance or one of the substances in the mixture is intended to enhance the long term availability to plants of micronutrients in the EU fertilising product, that substance shall be either a chelating agent or a complexing agent, and the following rules shall apply:
- (a) The chelating agent shall be an organic substance consisting in a molecule which:
  - (i) has two or more sites that donate electron pairs to a central transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn), magnesium (Mg), calcium (Ca) or cobalt (Co)), and

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

(ii) is large enough to form a five- or six- membered cyclic structure.

The EU fertilising product shall remain stable in standard Hoagland solution at pH 7 and 8 for at least 3 days.

(b) The complexing agent shall be an organic substance forming a flat or steric structure with one di- or tri- valent transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co)).

The EU fertilising product shall remain stable in water solution at pH 6 and 7 for at least 1 day.

- 4. Where the substance or one of the substances in the mixture is intended to improve the EU fertilising product's nutrient release patterns by delaying or stopping the activity of specific groups of micro-organisms or enzymes, that substance shall be an a nitrification inhibitor, a denitrification inhibitor or a urease inhibitor, and the following rules shall apply:
- (a) The nitrification inhibitor shall inhibit the biological oxidation of ammoniacal nitrogen (NH<sub>3</sub>-N) to nitrite nitrogen (NO<sub>2</sub>-), thus slowing the formation of nitrate nitrogen (NO<sub>3</sub>-).

The ammoniacal nitrogen (NH<sub>3</sub>-N) oxidation rate shall be measured either by:

- (i) ammoniacal nitrogen (NH<sub>3</sub>-N) disappearance, or
- (ii) the sum of nitrite nitrogen (NO<sub>2</sub>-) and nitrate nitrogen (NO<sub>3</sub>-) production with respect to time.

Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH<sub>3</sub>-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) forms ammonium ( $NH_4^+$ ) and urea ( $CH_4N_2O$ ).

- (b) The denitrification inhibitor shall inhibit the formation of nitrous oxide  $(N_2O)$  by slowing down or blocking the conversion of nitrate  $(NO_3$ -) to dinitrogen  $(N_2)$  without influencing the nitrification process as described in PFC 5(A).
  - Compared to a control sample where the denitrification inhibitor has not been added, an *in vitro* test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide  $(N_2O)$  based on an analysis carried out 14 days after application at the 95 % confidence level.
- (c) The urease inhibitor shall inhibit hydrolytic action on urea (CH<sub>4</sub>N<sub>2</sub>O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation. Compared to a control sample where the urease inhibitor has not been added, an *in vitro* test containing the urease inhibitor shall show a 20 % reduction in the rate of hydrolysis of urea (CH<sub>4</sub>N<sub>2</sub>O) based on an analysis carried out 14 days after application at the 95 % confidence level.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) form urea ( $CH_4N_2O$ ).

CMC 2: PLANTS, PLANT PARTS OR PLANT EXTRACTS

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

An EU fertilising product may contain plants, plant parts or plant extracts having undergone no other processing than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying or extraction with water or supercritical CO<sub>2</sub> extraction.

For the purpose of this point, plants include mushrooms and algae and exclude blue-green algae (cyanobacteria).

### CMC 3: COMPOST

- 1. An EU fertilising product may contain compost obtained through aerobic composting of exclusively one or more of the following input materials:
- (a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate biowaste collection at source;
- (b) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
- (c) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:
  - the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment,
  - sewage sludge, industrial sludge or dredging sludge, and
  - animal by-products or derived products falling within the scope of Regulation (EC) No 1069/2009 for which no end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
- (d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process provided that:
  - (i) the additive is registered pursuant to Regulation (EC) No 1907/2006<sup>(3)</sup>, with a dossier containing:
    - the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
    - a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (e) any material listed in points (a), (b) or (c) which:
  - (i) has previously been composted or digested, and
  - (ii) contains no more than 6 mg/kg dry matter of  $PAH_{16}^{(4)}$ .
- 2. The composting shall take place in a plant:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and
- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The aerobic composting shall consist of controlled decomposition of biodegradable materials, which is predominantly aerobic and which allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. All parts of each batch shall be either regularly and thoroughly moved and turned or subject to forced ventilation in order to ensure the correct sanitation and homogeneity of the material. During the composting process, all parts of each batch shall have one of the following temperature-time profiles:
- 70 °C or more for at least 3 days,
- 65 °C or more for at least 5 days,
- 60 °C or more for at least 7 days, or
- 55 °C or more for at least 14 days.
- 4. The compost shall contain:
- (a) no more than 6 mg/kg dry matter of  $PAH_{16}^{(5)}$ ;
- (b) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and
- (c) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (b).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (b) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

- 5. The compost shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
  - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %.
  - Criterion: maximum 25 mmol O<sub>2</sub>/kg organic matter/h; or
- (b) Self heating factor:
  - Definition: the maximum temperature reached by a compost in standardised conditions as an indicator of the state of its aerobic biological activity,
  - Criterion: minimum Rottegrad III.

### CMC 4: FRESH CROP DIGESTATE

- 1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:
- plants or plant parts grown for the production of biogas. For the purpose of this point, plants include algae and exclude blue-green algae (cyanobacteria);

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- (b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process provided that:
  - (i) the additive is registered pursuant to Regulation (EC) No 1907/2006<sup>(6)</sup>, with a dossier containing:
    - the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
    - a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (c) any material referred to in point (a) that has previously been digested.
- 2. The anaerobic digestion shall take place in a plant:
- in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and
- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:
- (a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;
- (b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Commission Regulation (EU) No 142/2011<sup>(7)</sup>;

(c)	thermophilic anaerobic digestion at 55 °C followed by composting in:		
	_	70 °C or more for at least 3 days,	
	_	65 °C or more for at least 5 days,	
	_	60 °C or more for at least 7 days, or	
		55 °C or more for at least 14 days;	

- (d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or
- (e) mesophilic anaerobic digestion at 37-40 °C followed by composting in:
  - 70 °C or more for at least 3 days,
  - 65 °C or more for at least 5 days,

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- 60 °C or more for at least 7 days, or
- 55 °C or more for at least 14 days.
- 4. Both the solid and the liquid part of the digestate shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
  - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %;
  - Criterion: maximum 25 mmol O<sub>2</sub>/kg organic matter/h; or
- (b) Residual biogas potential:
  - Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C;
  - Criterion: maximum 0,25 l biogas/g volatile solids.

# CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE

- 1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:
- (a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate biowaste collection at source;
- (b) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
- (c) living or dead organisms or parts thereof which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:
  - (i) the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment,
  - (ii) sewage sludge, industrial sludge or dredging sludge,
  - (iii) animal by-products or derived products falling within the scope of Regulation (EC) No 1069/2009 for which no end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
- (d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process provided that:
  - (i) the additive is registered pursuant to Regulation (EC) No 1907/2006<sup>(8)</sup>, with a dossier containing:
    - the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

_	a chemical safety report pursuant to Article 14 of Regulation
	(EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (e) any material listed in points (a), (b) or (c) which:
  - (i) has previously been composted or digested, and
  - (ii) contains no more than 6 mg/kg dry matter of  $PAH_{16}^{(9)}$ .
- 2. The anaerobic digestion shall take place in a plant:
- in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and
- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:
- (a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;
- (b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011;

(c)	thermophilic anaerobic digestion at 55 °C followed by composting in:			
	— 70 °C or more for at least 3 days,			
	— 65 °C or more for at least 5 days,			
	— 60 °C or more for at least 7 days, or			
	— 55 °C or more for at least 14 days;			

- (d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or
- mesophilic anaerobic digestion at 37-40 °C followed by composting in:

  70 °C or more for at least 3 days,
  65 °C or more for at least 5 days,
  60 °C or more for at least 7 days, or
  55 °C or more for at least 14 days.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- 4. Neither the solid nor the liquid part of the digestate shall contain more than 6 mg/kg dry matter of  $PAH_{16}^{(10)}$ .
- 5. The digestate shall contain:
- (a) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and
- (b) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (a).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (a) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

- 6. Both the solid and the liquid part of the digestate shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
  - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %.
  - Criterion: maximum 25 mmol O<sub>2</sub>/kg organic matter/h; or
- (b) Residual biogas potential:
  - Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C.
  - Criterion: maximum 0,25 l biogas/g volatile solids.

## CMC 6: FOOD INDUSTRY BY-PRODUCTS

- 1. An EU fertilising product may contain component material consisting of one of the following substances:
- (a) food industry factory lime, i.e. a material from the food processing industry obtained by carbonation of organic matter, using exclusively burnt lime from natural sources;
- (b) molasses, i.e. a viscous by-product of the refining of sugarcane or sugar beets into sugar;
- vinasse, i.e. a viscous by-product of the fermentation process of molasses into ethanol, ascorbic acid or other products;
- (d) distillers grains, i.e. by-products resulting from the production of alcoholic beverages;
- (e) plants, plant parts or plant extracts having undergone only heat treatment or heat treatment in addition to processing methods referred to in CMC 2; or
- (f) lime from drinking water production, i.e. residue which is released by production of drinking water from groundwater or surface water and consists, mainly, of calcium carbonate.

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- 2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006<sup>(11)</sup>, with a dossier containing:
- (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
- (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by point 6, 7, 8, or 9 of Annex V to that Regulation.

#### CMC 7: MICRO-ORGANISMS

An EU fertilising product belonging to PFC 6(A) may contain micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which:

- have undergone no other processing than drying or freeze-drying; and
- are listed in the following table:

Azotobacter spp.

Mycorrhizal fungi

Rhizobium spp.

Azospirillum spp.

### CMC 8: NUTRIENT POLYMERS

- 1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in points 1 and 2 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.
- 2. At least 60 % of the polymers shall be soluble in a phosphate buffer solution with a pH of 7,5 at  $100 \, ^{\circ}$ C.
- 3. The final degradation products shall be only ammonia ( $NH_3$ ), water and carbon dioxide ( $CO_2$ ).
- 4. The polymers shall not contain more than 600 ppm of free formaldehyde.

## CMC 9: POLYMERS OTHER THAN NUTRIENT POLYMERS

- 1. An EU fertilising product may contain polymers other than nutrient polymers only in cases where the purpose of the polymer is:
- (a) to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent'),
- (b) to increase the water retention capacity or wettability of the EU fertilising product, or
- (c) to bind material in an EU fertilising product belonging to PFC 4.
- 2. From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6).

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers.

- 3. For the polymers referred to in point 1(a) and (b), neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions of use in the EU fertilising product. The polymer shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil microorganisms as follows:
- (a) In the plant growth acute toxicity test, the germination rate and the plant biomass of the tested plant species grown on the soil exposed to the test material shall be more than 90 % of the germination rate and the plant biomass of the same plant species grown on corresponding blank soil not exposed to the test material.

The results shall be considered to be valid only if in the controls (i.e. blank soil):

- the seedling emergence is at least 70 %:
- the seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species;
- the mean survival of emerged control seedlings is at least 90 % for the duration of the study; and
- environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.
- (b) In the earthworm acute toxicity test, the observed mortality and the biomass of surviving earthworms in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if:
  - the percent mortality observed in the control (i.e. blank soil) is less than 10 %, and
  - the average loss of biomass (mean weight) of the worms in the blank soil does not exceed 20 %.
- (c) In the nitrification inhibition test with soil micro-organisms, the nitrite formation in soil exposed to the test material shall be more than 90 % of those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if the variation between replicate control samples (blank soil) and test samples is less than 20 %.

CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) NO 1069/2009

An EU fertilising product may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined in accordance with that Regulation, and which are listed in the following table and as specified therein<sup>(12)</sup>:

CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC

- 1. An EU fertilising product may contain by-products within the meaning of Directive 2008/98/EC, except<sup>(13)</sup>:
- (a) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,

Status: Point in time view as at 05/06/2019.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- (b) polymers,
- (c) compost, or
- (d) digestate.
- 2. The by-products shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing:
- (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
- (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by point 6, 7, 8 or 9 of Annex V to that Regulation.

3. From 16 July 2022, the by-products shall comply with the criteria established by delegated act referred to in Article 42(7). An EU fertilising product placed on the market after that date shall not contain by-products referred to in point 1 which do not comply with such criteria.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II. (See end of Document for details)

- (1) The exclusion of a material from CMC 1 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers, CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009 or CMC 11 on by-products within the meaning of Directive 2008/98/EC.
- (2) In the case of a substance recovered in the European Union, this condition is fulfilled if the substance is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (3) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (4) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.
- (5) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.
- (6) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (7) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).
- (8) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (9) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.
- (10) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene
- (11) In the case of a substance recovered in the European Union, this condition is fulfilled if the substance is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (12) The table will be established by delegated acts referred to in Article 42(5).
- (13) The exclusion of a material from CMC 11 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers or CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009.

### **Status:**

Point in time view as at 05/06/2019.

# **Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, PART II.